UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	**MDL No. 1456** **Master File No. 01- 12257-PBS** **Subcategory Case. No. 06-11337**
THIS DOCUMENT RELATES TO: *United States of America ex rel. Ven-A-Care of the Florida Keys, Inc., et al. v. Dey, Inc., et al.*, Civil Action No. 05-11084-PBS	**Hon. Patti B. Saris** **Magistrate Judge Marianne B. Bowler**

DEFENDANTS DEY, INC., DEY, L.P., AND DEY L.P., INC.'S REPLY IN FURTHER SUPPORT OF THEIR MOTION FOR PARTIAL SUMMARY JUDGMENT AND RESPONSE TO THE UNITED STATES' CROSS-MOTION FOR PARTIAL SUMMARY JUDGMENT

Dated: August 28, 2009

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PRELIMINARY STATEMENT[1]

Just prior to the filing of Dey, Inc., Dey, L.P. and Dey L.P., Inc.'s ("Dey") motion for summary judgment in this action, Plaintiff the United States (the "Government") voluntarily agreed to dismiss its common law fraud claims against Dey, Abbott and Roxane with prejudice. (*See* Dkt. 6163, Ex. 13). Now that the parties have completed discovery and have the opportunity to set forth the evidentiary record for the Court, the Government's decision is hardly surprising. As set forth in Dey's memorandum of law in support of its motion for partial summary judgment ("Moving Brief"), the record is clear that Dey was entirely forthcoming with the Government about the prices for its drugs: reporting its WACs,[2] its invoice prices for its drugs, to publishing compendia for publication alongside its AWPs, during the entire period at issue; sending its AMPs, fully discounted prices for its drugs, directly to CMS every quarter since 1991; and disclosing that its AWPs are set before launch, do not subsequently change, and are not reflective of prices paid in the market place in letters sent to Medicaid and Medicare since 1999. The evidence set forth in the Combined Memorandum of Defendants Abbott Laboratories, Inc., Dey, and Boehringer Ingelheim Roxane, Inc. and Roxane Laboratories, Inc. in opposition to the United States Cross-Motions for Partial Summary Judgment ("Combined Brief") makes clear that the Government was not deceived about Dey's AWPs but rather

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1 On these motions, Dey relies on the evidence set forth in Dey's Rule 56.1 Statement ("SOF"), the exhibits attached to the Declaration of Sarah L. Reid in Support of Dey, Inc., Dey, L.P., and Dey L.P., Inc.'s Motion for Partial Summary Judgment (Dkt. 6184) (annexing exhibits 1-296), and the Declaration of Sarah L. Reid in Support of Dey's Opposition to Plaintiffs' Motion for Partial Summary Judgment filed concurrently with this response (annexing exhibits 297-418) (hereinafter referred to as "Ex.__"), as well as on the affidavit of Pamela Marrs ("Marrs Aff."), and the declarations of W. David Bradford, Ph.D. ("Bradford Decl." and "Ex. 405"), and Lauren J. Stiroh, Ph.D. ("Stiroh Decl." and "Ex. 406"). Dey also cites to the United States' Dey and Common Statement of Facts ("US-D-SOF" and "US-C-SOF"), as well as Dey's Reply to its Statement of Facts ("Reply SOF"); Dey's Response to the United States' Statement of Facts as to Dey ("US-Dey-SOF-Response), and Defendants' Joint Response to the United States' Common Statement of Facts ("US-C-SOF-Response").

2 Capitalized terms and acronyms used here shall have the same meanings as in Dey's Moving Brief.

Medicaid and Medicare intentionally chose to use AWP as a payment benchmark for their own policy goals. State Medicaid Programs and Medicare intentionally paid profits on multiple source drugs, such as Dey's, for a variety of policy reasons such as encouraging generic usage, maintaining access, and cross-subsidizing inadequate dispensing fees.

Against this backdrop of pricing disclosure on the part of Dey and knowing policy choices on the part of Medicare and Medicaid, the Government seeks summary judgment against Dey on a False Claims Act ("FCA") claim. An examination of the full evidentiary record necessitates the denial of the Government's motion. The Government's case against Dey is premised on two fundamental points:

1. the Government's contention that Dey's AWPs – and for a brief period, its WACs for unit dose albuterol sulfate, as reported by First DataBank – do not comport with definitions of AWP and WAC that this Court articulated in other cases in which neither Dey nor the Government was a party; and

2. the Government's allegation that, prior to 1997, Dey "marketed the spread" for its albuterol and cromolyn products.

The Government has not moved on its FCA claim relating to Dey's published WACs for the 26 NDCs at issue, except for an isolated instance relating to one reported WAC, and has selectively chosen to seek full summary judgment in the Medicare context only on one DMERC for one drug for a limited time period, apparently leaving the remainder of its claims for trial.

The Government's motion fails on both the facts and the law. The pricing disclosures by Dey, coupled with the Government's informed decision to rely on AWP as a reimbursement benchmark requires summary judgment for Dey or at the very least raise triable issues of fact as to falsity, scienter, and causation, despite the Government's allusions to the "spread" on Dey's generic drugs and alleged "marketing the spread" by Dey's sales representatives. As the Moving Brief demonstrates at 38, the so-called "spread" on the subject drugs resulted from Dey's continuous lowering of the prices it charged its customers, not from manipulation of AWPs in an

attempt to deceive the Government. The evidence the Government relies on to support its allegations of "marketing the spread" is selective and limited to the early and mid-1990s, during the period where the spread for Dey's drugs was at its smallest. Finally, the Government's attempt to shoehorn this case into the Court's prior rulings made in different contexts and without benefit of the complete record does not provide a legal basis for granting summary judgment.

Indeed, the evidence the Government sets forth to support its FCA claims is so weak, and the concurrent evidence of Dey's pricing disclosures and the Government's knowledge is so strong, that Dey is entitled to partial summary judgment limiting the time frame for the Government's claims as set forth in its Moving Brief. Nor has the Government come forward with any evidence to controvert any of Dey's other grounds for partial summary judgment on damages. Dey is entitled to summary judgment on the issue of damages for all states where no states claims data was used, for all claims not paid on AWP or WAC, and on the Government's "joint harm theory" of Medicare liability. Next, the Government has utterly failed to come forth with any evidence linking Dey's alleged misconduct with an unjust enrichment claim. Finally, as set forth in the Combined Brief at 36-38, the Government has failed to show a basis to strike any of Dey's affirmative defenses.

ARGUMENT

I. THE COURT SHOULD GRANT DEY SUMMARY JUDGMENT AS TO CERTAIN CLAIMS CONCEDED BY THE GOVERNMENT

Dey is entitled to summary judgment on those claims for which the Government has conceded that it is not seeking damages:

- FCA damages in those instances where a state did not employ a "lower of" formula to determine Medicaid reimbursement (U.S. Dey Brief at fn13, p. 20);
- Medicaid damages for Texas, Ohio and Arizona (U.S. Dey Brief at fn12, p. 28);

- Medicare damages for instances when Dey is not included in an array (U.S. Combined Brief at fn12, p. 28); and

- Medicare damages for cromolyn (U.S. Dey Brief at fn12, p. 28).

II. IN ADDITION TO THE KNOWLEDGE SET FORTH IN THE COMBINED BRIEF, DEY'S EXTENSIVE PRICING DISCLOSURES RAISE ISSUES OF FACT WHICH PRECLUDE SUMMARY JUDGMENT AS TO THE USE OF DEY'S AWPS BY MEDICAID AND MEDICARE IN DETERMINING APPROPRIATE LEVEL OF PAYMENT TO PROVIDERS

A. CMS and The Medicaid State Agencies Had Extensive Knowledge of Dey's Pricing For The Subject Drugs Throughout the Relevant Time Period Yet Continued AWP-Based Reimbursement

The Government does not dispute that Dey provided both CMS and state Medicaid agencies with extensive pricing information from which they could have readily discerned differences between AWP and actual acquisition cost, and even mega spreads, for Dey's Subject Drugs. (Reply SOF ¶¶ 74, 76, 87, 91-3, 110-13, 115). The Government argues instead it should not be held accountable for such knowledge. This, however, misses the point: the extensive pricing information that Dey disclosed and Medicaid and Medicare's policy choices as set forth at length in the Combined Brief, at the very least create issues of fact which require a trial.

In its motion, the Government acts as if everyone had blinders on while dealing with the wealth of information available concerning Dey's prices for the Subject Drugs. Thus, the Government contends that Dey's reporting of WACs, which are Dey's actual invoice prices to wholesalers, to the same publications that it reported its AWPs was not sufficient to put Government agencies on notice because such agencies would have had to "piece together" the difference between the AWPs and WACs (*i.e.* they would have had to compare the two prices). Since these prices often appeared side-by-side, the only "analysis" such agency personnel would have had to engage in would have been looking at the price listed in the AWP column, then looking at the price listed in the WAC column, one column to the left. (*See* Ex's413-416). Not

surprisingly, the Government did engage in exactly this kind of analysis. For example, it produced printouts of Red Book pricing data for Dey's drugs from April of 2000 that display the AWPs and WACs for Dey's albuterol sulfate unit dose and ipratropium bromide side by side with handwritten notations next to the entries for the Dey Subject Drugs, indicating that someone had in fact reviewed the prices listed therein. (*See* Ex's 417; 418). In fact, two separate OIG reports issued in 2002 engaged in this type of analysis for both ipratropium bromide and albuterol sulfate. (*See* Ex 54, at p. 8; Ex. 60, at p. 11). In short, the Government's burden complaints shortchange its own agencies.

Next, the Government contends Dey's reporting of AMPs does not constitute "government knowledge" because federal law requires that AMPs be kept confidential and that the Government could not use them for any purpose other than the rebate program. The Government is simply wrong; nowhere does the statute prohibit CMS from comparing AMPs to published prices. The actual confidentiality provision in the Rebate Agreement states that AMPs "will not be disclosed by the Secretary or State Medicaid agency in a form which reveals the Manufacturer, or prices charged by the Manufacturer." (*See* Ex. 34, at VII(a)). In 2001, the OIG issued a report suggesting that CMS could properly use AMPs to calculate reimbursement payments, or at least provide AMPs to the states. (*See* Ex. 38, at pp. 20-22). Indeed, California, Maine, Texas, and Vermont all require drug manufacturers to report AMPs directly to their Medicaid programs. (*See* US-C-SOF-Response at ¶¶ 100). It is also uncontested that for generics, it was simple to compute the AMPs from the URAs which CMS sent to the states. (*See* SOF at ¶ 99-101). Moreover, the confidentiality argument misses the point. That CMS believed it had to keep the AMPs it received from Dey confidential does not change the fact that, throughout the relevant time period, Dey reported its AMPs directly to CMS, which are almost

identical to the prices the Government now contends Dey should have been reporting as its AWPs, and that CMS was therefore fully aware of these prices. *See* SOF at ¶ 105. Despite continuously receiving Dey's AMPs since 1991, CMS continued to approve state plan amendments using the higher AWP prices, as they do today. (Common SOF ¶¶ 62-66; SOF ¶ 216). In addition, CMS explicitly and repeatedly directed Medicare DMERC's to use AWP "as reflected in sources such as the Red Book, Blue Book or Medispan". (SOF 183).

Next, the Government's contention that FSS prices were not sufficient to constitute "government knowledge" is refuted by the Government's own expert, Simon Platt. The "average sales prices" that Mr. Platt calculated and the Government relies to show that Dey's AWPs were allegedly false track the FSS prices for the Subject Drugs almost exactly. *See* Ex 406, Figures A-K. Yet, bizarrely, the Government contends that these public FSS prices did not sufficiently inform the Government of Dey's actual prices because they did not adequately reflect the prices that Medicaid and Medicare providers pay for the Subject Drugs. (*See* US Dey Brief at p. 16). The Government cannot have it both ways. If these prices were not the prices that Dey should have been reporting, then the Government cannot rely on them to demonstrate that Dey's prices were false; if these were prices that Dey should have been reporting, then the Government had them all along and Dey cannot be liable.[3]

The Government attempts to side-step its extensive knowledge of Dey's pricing by contending that it did not "approve" of Dey's price reporting practices and that Dey did not rely on any such "approvals." As set forth in the Combined Brief at 20-23, there is simply no requirement of express approval or reliance to establish a defense to an FCA claim: knowledge

[3] These competing views within the Government's own filings demonstrate a fundamental flaw in the Government's case: CMS has never articulated a meaningful definition of AWP. It is impossible to hold Dey liable for reporting "false" AWPs when the Government's own lawyers and experts cannot agree as to what a "true" AWP should be.

and acquiescence is all that is needed. The Government's contention that the OIG reports and the Government's investigative efforts do not demonstrate government approval but rather disapproval of Dey's conduct simply raises another issue of fact. The OIG reports are typically critical not of drug manufacturers but of CMS for continuing to use AWP as a basis for reimbursement. For instance, in the report "Medicare Reimbursement for Albuterol" OEI-03-00-00311 (2000), the OIG stated "This report found that Medicare would save between $47 million and $209 million by lowering its reimbursement amount for albuterol to prices available through other sources." (*See* SOF at ¶ 117). In short, the law is that even if the Government is not happy about paying the claim, there can be no "false claim" if the Government has knowledge of the alleged false nature of the claim but pays it anyway. *See United States ex rel. Englund v. Los Angeles County*, No. CIV. S-04-282 LKK/JFM, 2006 WL 3097941 (E.D. Cal. Oct. 31, 2006), *12, 14 (finding no FCA because the Government had knowledge of the alleged falsity but paid the claim anyway, even though government officials described the practice underlying FCA allegations as "a total scam" and "legal money laundering,").

B. There Is No Basis To Find Dey's AWPs Were False As A Matter of Law

The Government contends Dey's AWPs are false as a matter of law because they do not comport to a definition of AWP that was first articulated by this Court in November of 2006, when it had not yet had the opportunity to examine the full record of CMS and State agency knowledge and action. However, as the Combined Brief demonstrates, CMS never understood AWPs to be an actual average of prices paid to wholesalers. Indeed, CMS has never articulated a definition of AWP and, as discussed in the Combined Brief at 23-29, CMS officials understood AWP to be an undefined, unauditable term. Since there is no objective standard against which AWP can be measured, a jury could reasonably find Dey's AWPs cannot form the basis of liability under the FCA. *See id.*

In the absence of any definition from the Government, in 1999, Dey began disclosing its understanding of the term AWP – namely that it was a price set prior to the launch of a drug and generally not subject to change and thus not reflective of prices actually paid for the drugs – in its price notification letters, which Dey sent directly to DMERCs and state Medicaid agencies. *See* SOF at ¶¶ 148-153. As the letters made clear, Dey's AWPs did not represent actual prices paid for Dey's drugs and it was Dey's practice to set its AWPs before a product was first sold and to not subsequently change them. *See* SOF at ¶¶ 153. Dey invited recipients of the letter to contact Dey regarding the disclosure, but no state Medicaid official or DMERC employee ever did. *See* SOF at ¶¶ 154-157. The Government does not contend that the AWPs for the Subject Drugs do not comport with the statements made by Dey in its price notification letters. When the Government has full knowledge of the allegedly false statement or claim, there can be no finding of "falsity" under the FCA. *See* Combined Brief at 20-23. Coupled with Dey's extensive pricing disclosures to the Government, the letters, at a minimum, raise a triable issue of fact as to "falsity" under the FCA.

C. There Is No Basis to Find Scienter As A Matter of Law

The Government's motion as to scienter fails for the same reasons. To prove scienter, the Government must show that Dey acted with (1) actual knowledge, (2) deliberate ignorance, or (3) reckless disregard when reporting AWPs to the pricing compendia. *See* Combined Brief at 30-32. The Government contends that it has satisfied the "knowledge" requirement of the FCA because Dey knew that its AWPs did not comport to a definition of AWP that this Court articulated November of 2006, without the benefit of a complete record. But again, it is a question of fact as to whether Dey knowingly violated that definition, where there is substantial evidence that Dey's understanding of the term comported with the understanding of CMS, OIG, and Medicaid agencies at that time.

In the absence of any guidance from the Government, Dey did disclose its understanding of AWPs and made clear that its AWPs did not reflect actual transaction prices. (SOF 148-157). In addition to Dey's pricing disclosures, Dey publicly reported its WACs, provided its AMPs directly to CMS, and negotiated FSS prices directly with the Government. (SOF 110-116). Thus, as far as Dey was concerned and as a jury could reasonably find, the Government had extensive knowledge of all such prices and Dey had no reason to believe that it was reporting "false" AWPs or deceiving anyone into "overpaying" providers.

The Government's allusions to Dey's alleged knowledge of the "spread" and alleged efforts by Dey employees to "market the spread" are not probative of the question of Dey's scienter. As the Government's brief makes clear, the relevant question on the "knowledge" element of an FCA claim is whether the defendant knew the information was false, or acted with deliberate ignorance or reckless disregard to its truth or falsity. *See* U.S. Dey Brief at 23. The existence of a "spread" on the Subject Drugs, or Dey's alleged efforts to "market the spread," do not shed light on the question of whether Dey believed or intended its AWPs to be "false."

Dey did not manipulate its AWPs to create or increase a spread on the Subject Drugs. As Dey explicitly disclosed in its price notification letters, and as the charts prepared by the Government's own expert, Simon Platt, confirm, Dey generally did not change the AWPs on the Subject Drugs at all. (*See* Reply SOF at ¶¶ 148-153; Henderson Decl., Ex. 19, Charts A1-A13). As discussed in the Moving Brief at 38, the "spreads" on the Subject Drugs came about because Dey was constantly lowering the prices that it charged its customers; this, too, was clearly disclosed in Dey's publicly available WACs, and the AMPs Dey reported directly to the Government. (*See* Ex. 406, Figures A-K). The "spreads" are evidence of the stiff competition that Dey faces in the market place, not of some sinister scheme by Dey to defraud the

Government.[4]

Likewise, whether Dey sales representatives discussed the reimbursement spreads on the Subject Drugs with Dey's customers is irrelevant to whether Dey knew or should have known that its AWPs were "false." Indeed, as discussed in the Combined Brief at 12-20, evidence in the record confirms that the existence of spreads in reimbursement was knowingly caused by CMS and state Medicaid agencies, who all chose to reimburse based on AWP in spite of their knowledge that AWP did not approximate providers' acquisition costs. (*See* Combined Brief at 12-20). That some of Dey's employees purportedly discussed this when they met with customers – which Dey does not concede – is not evidence that Dey knew that its AWPs were false. In any event, the Government has not adduced any evidence of what it alleges is "spread-marketing" by Dey after 1997, and the evidence it has adduced basically consists of culled portions of launch documents for albuterol and cromolyn when the spreads were at their lowest, a reimbursement worksheet used inconsistently during portions of a two year period in an effort to switch from albuterol multi-dose to albuterol unit-dose and the testimony of a few employees taken out of context. *See* US-D-SOF-Response at ¶¶ 152-157. In fact, one of the highlights of the Government's evidence on marketing the spread is the testimony of a former low level sales representative now incarcerated for twenty years to life for lying and impersonating professionals in order to sexually assault female victims. At his deposition, this witness, who was fired by Dey in the mid-1990's, obligingly testified that he "marketed the spread" on a drug that Dey did not

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[4] Indeed, as the other AWP actions pending in this MDL make clear, the existence of Medicaid and Medicare reimbursement "spreads" on drugs, particularly on generic drugs, is an industry-wide phenomenon. (*See* Complaint in the action *California ex rel Ven-A-Care v. Abbott Labs* at ¶¶ 4-21, Ex. A (action brought by California naming 17 separate drug manufacturers as defendants); Complaint in the action *City of New York v. Abbott Labs* at ¶¶ 45-83 (action brought by New York Counties naming 34 separate drug manufacturers as defendants); Complaint in the action *U.S. ex rel Ven-A-Care v. Actavis*, at ¶¶ 16-24, Ex. A ((federal qui tam action naming eight of the ten largest generic drug manufacturers as defendants and alleging over 1000 NDCs at issue).)

even sell until after he was fired. He also testified he was a "detainee" who was about to be released from prison, despite his 20 year sentence. *See id.* at ¶ 104 for a complete recital of the unreliability of this witness.

D. There Is No Basis to Find Causation As a Matter of Law

For the reasons set forth in the Combined Brief, the Government's motion for causation fails as well. The causal link between Dey's AWP reporting and any alleged "false claim" is particularly weak, because Dey not only provided the Government with extensive information regarding its prices, but also expressly disclosed its understanding of AWP to the Government. (SOF at ¶¶ 148-157).

Causation also presents a particular issue of fact on the Government's cross-motion on 18 CIGNA ipratropium arrays for 1997 Q2 through 2001 Q3, selected by the Government out of the over 228 arrays considered by the Government's expert, Dr. Duggan. (Ex. 405 ¶ 12). Because a defendant will only be liable for false claims his conduct proximately caused, and not for claims resulting from an intervening cause, CIGNA's decision to include or exclude particular products in the Medicare arrays defeats causation here. *See United States ex rel. Cantekin v. Univ. of Pittsburgh*, 192 F. 3d 402, 416 (3d Cir. 1999); *Russo v. Baxter Healthcare Corp.*, 140 F.3d 6, 11 (1st Cir. 1998). Carolyn Helton of CIGNA[5] testified that she would have to use her discretion on whether to add a price for a particular code to an array. (Dey's Response to US-SOF ¶ 205).[5] She "generally did not select drugs with special sized packaging, or convenience items such as flip-top vials, carpu-jets, tubes, and others." (*Id.*). Furthermore, "[t]he policy to not select such items for inclusion in arrays was developed and implemented over a period of time by DMERC

[5] In support of their cross-motion on this issue, the Government relies on the Declaration of Carolyn Helton of CIGNA. Dey objects to the Government's reliance on Carolyn Helton's Declaration, which was submitted after the close of discovery, contradicts pre-existing facts in the record, and because Dey has not yet had the opportunity to conduct discovery with respect to Ms. Helton's declaration.

representatives in consultation with HCFA officials. (*Id.*). The Medicare Claims Processing Manual instructs carriers, in determining AWPs and payment allowance limits, to exclude certain products, such as drugs marked preservative free. (*Id.*).

The carrier's discretion can be seen in the exclusion/inclusion of Dey's preservative free products. Many of Dey's products were preservative free and some were listed as such in the Red Book. For example, in the 1998 Red Book, Dey's 2.5 ml 30s UD is listed as "PF" or preservative free. (*Id.*). Yet, in some arrays, contrary to the Medicare Claims Processing Manual, Dey's preservative free products are included. (*Id.*). Individuals at the carriers, including CIGNA, made determinations whether to include or exclude certain products in particular array, and those decisions were based on what AWPs "tended to increase the price". (*Id.*). Manufacturers did not include their products in arrays, individuals at the carriers did. The number of products and identity of those products included in a particular array affects the median calculation, and this can change across DMERCS. (Ex. 405 at ¶ 12). The Government should not be allowed to engage in piecemeal adjudication of its Medicare claim when it has conceded that issues relating to the remaining DMERCs, drugs, and time frames must be left for trial, including even ipratropium after 2003. This is both inefficient and potentially confusing to a jury.

In addition, payment rates and methodologies for the Medicare program are set by Congress and CMS, not Defendants. (SOF at ¶¶ 174-206). Because a jury could reasonably conclude that a DMERC's decision as to selection for the arrays, as well as the CMS directive to rely on compendia prices, were the proximate causes of the presentment of allegedly false claims based on AWP to the Medicare program, the Court should deny the Government's motion.

III. PARTIAL SUMMARY JUDGMENT SHOULD BE GRANTED LIMITING THE TIME FRAME FOR ANY RECOVERY

A. The Court Should Grant Dey Summary Judgment on All of the Government's FCA Claims From 1997 to the Present for Dey's Albuterol Sulfate and Cromolyn, and as of 1999 for All of Dey's Drugs

As the evidence discussed above and in Dey's Moving Brief at 15-24 makes clear, by 1997, the Government was fully aware of the pricing for Dey's albuterol sulfate and cromolyn. By 1999, it was also aware of the pricing for ipratropium bromide, as well as the manner in which Dey set its AWPs. Accordingly, as set forth in the Moving Brief, there is no basis to hold Dey liable under the False Claims Act after 1997 for albuterol sulfate and cromolyn, and after 1999 for all of the Subject Drugs. At the very latest, the Court should cut off liability from 2001, at which point this Court has held there was a "perfect storm" of information concerning AWP spreads, brought about in large part by the Government's own investigative efforts. *See In re. AWP Litig.*, 491 F. Supp. 2d 20, 41 (D. Mass. 2007); Moving Brief at 23-24.

B. Alternatively, Due Process Bars the Government's Claims After 1997

Dey should prevail on its due process claim because it has suffered actual prejudice. The Government has been obtaining information about Dey for almost 11 years, since the Government served its the first subpoena on or about October 31, 1997. (SOF 144). Indeed, the vast majority of the Dey documents cited by the Government were produced by Dey in response to Government subpoenas prior to the unsealing of this case. In contrast, Dey has conducted approximately a year and a half of discovery beginning in 2007. During that short discovery period, it became evident that the passage of time had rendered witnesses unavailable, memories deteriorated, and the documents lost or destroyed.[6]

For example, Dey attempted to depose Dr. Metzger, who served as Medical Director of

[6] Dey refers the Court to the motions for spoliation filed by Abbott and Dey, as well as their reply memoranda, for additional, specific, examples of lost evidence. *See* Dkts. 6097, 6110-11; and 6368.

Palmetto from 1994 to 2000. Palmetto was the DMERC with the largest number of Medicare claims for Dey' drugs. Dr. Metzger was involved in an OIG investigation relating to fraudulent claims submitted by providers in the Miami area.[7] Dr. Metzger was not able to testify for medical reasons which arose after the Complaint in this case was first filed under seal. (*See* Ex. E to Dkt. 6111). Dey has also been unable to depose Robert Katz because of his medical condition leading to memory loss. (*See* Ex. E to Dkt. 6111). Mr. Katz worked at the OIG's Philadelphia Regional Office and served either as a project leader or program analyst for four of the OIG reports that specifically deal the acquisition cost for albuterol sulfate, one of the Dey Subject Drugs.[8]

Numerous CMS and OIG witnesses could not remember certain key events and details because of the passage of time. For example, Larry Reed, who served as the Branch Chief of Medicaid Non-Institutional Payment Policy Branch from 1990-1995 could not remember whether he was aware of cross-subsidization in 1993 because his memory had faded. (Ex 402 at 691:2). Other examples include Susan Gaston, who served as the CMS Health Insurance Specialist from 1991 to 2003, setting FUL's for some of Dey's Drugs, who agreed that her "memory had faded." (Ex. 412 at 353:11-354:8). Robert Vito, Deputy Regional Inspector General (1990-1995) Regional Inspector General (1995- Present) could not remember details regarding a key meeting in September 1993 between OIG officials and state Medicaid officials discussing the price of generic drugs because of the passage of time. (Ex. 403 at 471:3-18). Linda Ragone's memory had also faded concerning OIG reports she worked on which studied

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7 "Review of Payments for Inhalation Drugs Made by Region C Durable Medical Equipment Regional Carriers" (A-06-00-00053)

8 HHS-OIG "Medicare Payments for Nebulizer Drugs" OEI-03-94-00390 (February 1996) (Program Analyst); HHS-OIG, "A Comparison of Albuterol Sulfate Prices" OEI 03-94-00392 (June 1996) (Program Analyst); HHS-OIG, "Suppliers' Acquisition Costs for Albuterol Sulfate" OEI-03-94-00393 (June 1996) (Project Leader); and HHS-OIG "Questionable Practices Involving Nebulizer Drug Therapy" OEI-03-94-00391 (March 1997) (Project Leader).

prices for Dey's drugs. (Ex. 404 at 231:1-232:15). Ms. Ragone testified that had she been asked questions in 1997, there was a "better chance" that she would remember it than if she was asked it "eleven years later". *Id*.

Finally, numerous documents have been lost or destroyed, including relevant e-mails. For example, Bruce Vladeck, CMS Administrator between May 1993 and September 1997, was an "extensive e-mailer" who "could very well have" used e-mail to discuss drug reimbursement issues. (Ex. GG to Dkt. 6097 at 102, 309-10). Ven-A-Care's earliest communications with CMS were sent directly to Dr. Vladeck (see, e.g., Ex. C; Ex. D; Ex. HH; Ex. II to Dkt. 6097), and several important events occurred during Dr. Vladeck's tenure, including CMS's proposal to remove AWP from Medicare's reimbursement formula, OIG's issuance of numerous AWP reports, and Barron's publication of its "Hooked on Drugs" article. These events would likely have triggered relevant emails and other correspondence, but Dr. Vladeck's files no longer exist. (Ex. FF to Dkt. 6097 at 175-77, 235-36).

The Government relies heavily upon the fact that Dey was apprised of the lawsuit. This type of notice does not change the fact that the Government engaged in one-sided discovery for nine years. During this time period, Dey was powerless to take discovery of the Government, resulting in demonstrable prejudice. Given the record of actual prejudice, this Court should find that the Government's intentional delay in unsealing this case was done either for a tactical advantage or in bad faith.

"In 'bad faith' cases, the government intentionally acts to delay; and the tactical advantage sought *is* the prejudice to the defendant which the government anticipates will flow from the delay." *U.S. v. Foxman*, 87 F.3d 1220, 1223 n.2 (11th Cir. 1996) (emphasis in

original).[9] Such is the case here. During this nine-year sealed period, the Government made the tactical decision to intentionally pursue extensive discovery of Dey, while taking absolutely no steps to preserve evidence or witnesses that would be helpful to Dey's defense. During the nine-year seal period, the Government subpoenaed documents from Dey; created an electronic database for the storage and review of those documents; coordinated discovery efforts with state Medicaid Fraud Control Units; interviewed witnesses; retained an expert to assist with damages calculations; and developed a computer model to assess damages. (SOF 143, Response to Dey-SOF 143). The Government can point to no litigation hold issued prior to 2003, and the holds instituted in 2003 and 2004 that it does reference were issued in a separate case. (Dkt. 6270 at 23).[10] It was not until 2007 when the Government issued a case-specific discovery hold to preserve evidence necessary to Dey's defenses, ten years after it first began conducting discovery of Dey. *Id*.

The due process standard applied by the Seventh Circuit is the proper standard for a showing of a due process violation. As found by the court in *Sowa* (also cited to by the Government), once a defendant has proven actual and substantial prejudice, the Government must come forward and provide its reasons for the delay. *U.S. v. Sowa*, 34 F.3d 447, 451 (7th Cir. 1994). Not only has the Government not come forward, it has blocked discovery into the reasons for the requests for extensions and the intention of the Government in requesting those extensions, including seeking and obtaining protective orders against such discovery. (See Dkt. 5356-7; Ex 408). The Government should not be allowed to use the claim of privilege as both a

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9 The Court in *Foxman* goes on to state that "intentional government acts designed to obtain a tactical advantage which only *incidentally* cause delay have never been ruled out as a potential basis for due process violations." *Id*. (emphasis in original).

10 The Government's spoliation of documents and witnesses in this case is the subject of Defendants motion for sanctions, currently pending before the Court.

sword and a shield, claiming privilege to avoid discovery on one hand, and then claiming that the absence of evidence blocked by that privilege is dispositive in defeating Dey's due process claim. "Particularly in a civil case, a privileged party cannot fairly be permitted to disclose as much as he pleases and then to withhold the remainder to the detriment of the defendant." *Greater Newburyport Clamshell Alliance v. Public Service Co.*, 838 F.2d 13, 20 (1st Cir. 1988) (citing 8 Wigmore On Evidence, § 2327 at 635-36 (McNaughton rev. 1961)).

IV. THE COURT SHOULD GRANT DEY SUMMARY JUDGMENT AS TO DAMAGES ON CERTAIN CLASSES OF ALLEGEDLY FALSE CLAIMS

A. Dey is Entitled to Summary Judgment on All Claims Not Paid on the Basis of Its Published AWP or WAC

This Court should grant Dey summary judgment as to all claims paid by Medicaid or Medicare on bases other than Dey's published prices. As set forth in Defendants' Combined Brief at 41-42, neither the Government nor its damages expert has shown or can show that the Government has suffered damages "because of the act of" Dey. 31 U.S.C. § 3729(a). The Government has also failed to provide evidence that Dey's published prices caused the payment of claims paid on the bases of MAC, FUL, U&C, and other unidentifiable bases. The Government explicitly does not claim that these other payment bases are false or fraudulent.[11] In keeping with this Court's prior orders in *In re Pharm. Indus. Average Wholesale Price Litig. (California ex rel. Ven-A-Care of the Fla. Keys, Inc. v. Abbott Labs., Inc.*, 478 F. Supp. 2d 164, 180 (D. Mass. 2007) and *Massachusetts v. Mylan Labs.*, 608 F. Supp. 2d 127, 148 n.4 (D. Mass. 2008), this Court should grant summary judgment on all claims not paid based on a compendia-

[11] For example, in the Government's response to Dey's Statement of Undisputed Materials Facts, Dkt. 6297, the Government does not dispute that certain states did not rely exclusively on published prices for setting MACs and further states that "[t]he Plaintiffs' theory of recovery and damages model are not based upon Dey's false price statements causing inflated MACs." (Response to ¶ 235). Furthermore, the Government states that it is not proceeding on a "FUL theory of liability" (Response to ¶ 244) and that it is not the Government's contentions that the Usual and Customary charges submitted by providers are in any way fraudulent. (Response to ¶ 256).

reported prices, including claims based on MAC, FUL, U&C, and other unidentifiable bases.

B. Dey is Entitled to Summary Judgment on all Damages Not Based on Actual State-Level Claims Data

This Court should grant Dey summary judgment on the issue of damages for the 33 states (and Washington D.C). that Plaintiffs' expert, Dr. Duggan, extrapolated damages. Summary judgment is warranted for these damage claims because (1) Dr. Duggan's extrapolation is an unreliable measure of damages; and (2) the Government cannot prove the payment bases, and therefore liability, for these extrapolated claims.

1. Dey is Entitled to Summary Judgment on Extrapolated Damages Because Dr. Duggan's Extrapolated Damages Are Not Reliable

This Court should grant summary judgment for all extrapolated claims because Dr. Duggan's extrapolation is not reliable for numerous reasons and is susceptible to significant error.[12] Employing Dr. Duggan's own methodology to available state claims data for an additional sixteen states produced "differences" *more than 20% larger* than identical calculations using the state-level claims data Dr. Duggan had but did not use in his calculations. For Dey, Dr. Duggan examined the state-level claims data for 14 states, combined that data with aggregate data for time periods for which he was missing state-level data, and came up with a damage estimate. (US-C-SOF ¶¶ 118, 129, 151). Dr. Duggan then extrapolated that estimate to the aggregate data for the remaining states for which the Government is seeking damages. (US-C-SOF ¶¶ 155-156). Dr. Duggan admits that even when he did have the state-level claims data, he did not use it to calculate damages in all cases. (US-C-SOF ¶ 117). When Dey's expert used Dr. Duggan's own methodology to examine state-level claims data for an additional sixteen states, the result was over 20% lower than Dr. Duggan's extrapolated damage estimate for those same

[12] The Government repeatedly states that that Dr. Duggan's analysis of claims-level data is reliable because it covered 63-68% of total spending. However, when the aggregate data is taken out, the state level data Dr. Duggan actually considered only amounts to less than 55%. (Ex. 405 at ¶ 2).

sixteen states. (Ex. 405 at ¶ 7, Figure 3). An average 20% rate of error across just an additional 16 states demonstrates that Dr. Duggan's 34 state extrapolation unreliable. This rate of error cannot be acceptable when the FCA allows for treble damages. In the case cited by the Government in support of its extrapolation, this Court excluded expert testimony on extrapolation when faced with "evidence that the technique is susceptible to manipulation and significant error." *United States ex rel. Loughren v. UnumProvident Corp.*, 604 F. Supp. 2d 259, 269 (D. Mass. 2009). That is certainly the case here.

2. The Government Cannot Prove Liability or Causation for Any Claims Not Supported By State-Level Claims Data

The Government has taken the position that state-level claims data is not necessary for it to prove its case. It instead relies on aggregate data and extrapolation to evidence alleged false claims and to calculate supposed damages. (US-C-SOF 116-119). In addition to causing grossly inflated damages, the data relied upon by the Government is simply not sufficient to prove false claims or damages under the FCA as a matter of law. The claims-level, contemporaneous state claims data is not only the best source that shows what a state Medicaid agency paid for particular claims, but the state-level claims data is often the only place that accurately documents the payment basis of particular claims. (SOF 287-290; Ex. 405 ¶ 3). Furthermore, without state level claims data it is not possible to determine whether the states were following their stated reimbursement policy, which defeats causation. *See* Combined Brief at 32-36. For Dey to be able to apply the principles from this Court's prior rulings in *California ex rel. Ven-A-Care of the Fla. Keys, Inc. v. Abbott Labs., Inc.* and *Massachusetts v. Mylan Labs.* to eliminate claims paid on bases other than published prices and lower its damage exposure, Dey needed access to the state-level claims data. (Ex. 405 ¶ 3; SOF 287-290) Accordingly, Dey made a discovery request in January, 2008 seeking complete claims data from all fifty states. (Dkt. 5765 at ¶ 1). Dey

made numerous follow-up requests for the state level claims data, yet, a month before the close of discovery, the Government had not produced any claims data from eighteen states and had failed to provide complete claims data that covered the entire time period at issue and the scope of Dey's discovery request for any single state. (Dkt. 5765 at ¶¶ 3-7). At a hearing before the Court, counsel for the Government stated "I think probably every state has claims data. They process claims. We have not had, quite frankly, the resources to go out and – it's very time consuming to collect this data, so we have not done it for all fifty states, and some states simply haven't produced it to us. So we just don't have it all, and we're unlikely to get much more." (November 13, 2008 Hearing Tr. At 44:11-17). Following that hearing, Dey served subpoenas on 38 states in an attempt to obtain additional claims data, and was able to obtain additional data from several additional states. (Dkt. 5765 at ¶ 9-11).

Because the Government chose not to obtain state level claims data for all states, its expert, Dr. Duggan, instead uses aggregate claims data and damage extrapolation to calculate damages for the remaining states. (US-C-SOF ¶ 155-6). Its excuses for not providing the evidence to support its damages, and the evidence needed by Dey to reduce the alleged damage claims against it, do not provide this Court with reason to deny Dey's motion.

Not only is state-level claims data necessary to show liability pursuant to 31 U.S.C. § 3729(a), but because the aggregate data either does not contain payment bases or has deficiencies which make the calculation of payment bases difficult, and because this aggregate data is then used in various extrapolation exercises, there is no way to separate out the proposed damages that are derived from claims that were paid on the basis of Dey's allegedly false AWPs and WACs from those claims that were paid on MACs, FULs, U&C, or other unidentifiable bases. Dey is entitled to summary judgment for all states and time periods where the Government does

not calculate damages using the actual state-level claims data.

C. The Government Has Provided No Evidence or Legal Basis For Combining Damages Alleged To Be Caused By Dey And Roxane.

This Court should grant Dey's Motion for summary judgment on the issue of combined Dey and Roxane damages for ipratropium bromide under Medicare because the Government has not put forth any cognizable basis for its "joint impact theory." [13] This Court has already rejected the vague theory put forward by the Government and its experts: "[g]iven that there are no claims or evidence of conspiracy or joint enterprise, the pertinent legal question is whether [a defendant] can be said to have *individually* caused the plaintiffs' injuries." *In re Pharm Indus. Avg. Wholesale Price Litig.*, 491 F. Supp. 2d 20, 99 (D. Mass. 2007) (emphasis added). Indeed, the Government instead alleges that the evidence indicates aggressive price competition between Dey and Roxane. (US-D-SOF ¶ 145).

The Government's joint impact theory seeks damages "even though any one manufacturer's AWP, viewed in isolation, had no effect on the median" (US-D-Brief at 27). But, this Court has already held that for multi-source drugs in the Medicare context, pricing is "a legal cause of plaintiffs' injury only when reporting a true AWP would have actually shifted the median". *In re Pharm Indus. Avg. Wholesale Price Litig.*, 491 F. Supp. 2d at 99.

Furthermore, because Dey can only be the legal cause for those injuries it "individually caused," the Government cannot prevail on any claims in which it calculates damages based on changing both Dey and Roxane's AWPs absent proof of conspiracy or joint enterprise. 491 F. Supp. 2d at 99. In their statement of facts, the Government makes it clear that the reason for seeking joint damages is because it enables their expert to come up with much larger numbers by

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[13] It should be noted that the Government has not moved for summary judgment for its "joint impact" theory. (US-Dey-Brief at fn 9, p. 6).

changing the AWPs of both Dey and Roxane. (US-D-SOF at 226). But, the Government cannot show that Dey individually caused the larger amount. The Government has not presented evidence that Dey had any understanding of Roxane's pricing, nor that Dey understood that its products were listed in arrays with Roxane's products. The Government has not alleged or put forward any evidence that Dey had any control over Roxane's prices. The False Claims Act is a punitive statute providing for treble damages. To allow damages to be astronomically inflated by calculating amounts jointly without any basis is particularly troubling.[14] This Court should grant Dey's motion for summary judgment with respect to these claims because the Government has not come forward with any legal nor factual support to support its novel theory.

V. THIS COURT SHOULD DENY THE UNITED STATES' CROSS-MOTION FOR PARTIAL SUMMARY JUDGMENT ON DEY'S 1995 ALBUTEROL FDB WAC

In its cross-motion, the Government does not seek summary judgment as to Dey's WACs as a whole and leaves for trial whether such compendia prices were false, were intended by to cause Medicaid to pay false claims, and whether such published prices caused any actual overpayments. Instead, the Government focuses on the WACs for Dey's albuterol sulfate unit dose products that Dey reported First DataBank, as opposed to Red Book or Medispan, from June 1, 1995 to December 4, 1995 but continued by First DataBank until December 31, 1997. The Government contends that these WACs were "false" because they do not comport to the definition of WAC that was articulated in this Court's December 2008 opinion in *Mass. v. Mylan* and adopts the same arguments as to causation, materiality and scienter that it asserts for Dey's AWPs. *See* US Dey Brief at 12-13, 19-21, 24.[15]

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[14] The cases cited by the Government in an attempt to support their theory are inapposite, as they rely on tort cases relating to joint and several liability.

[15] Dey's WAC prices comport with the statutory definition of WAC enacted by Congress in 2003. 42 U.S.C. 1395w–3a(c)(6)(B).

The evidentiary record on the reporting of this FDB WAC at the very least raises material issues of fact. A jury could reasonably conclude based on that record that a state Medicaid official knew of and approved the WACs in question and that Dey relied on this approval, which would effectively negate the falsity and scienter elements of the FCA claim. *See Mylan Labs* 608 F. Supp. 2d at 148-49. The evidence shows that in the second half of 1994, Dey began to receive complaints from its customers that the spreads from reimbursement payments from the Florida and Texas Medicaid programs for Dey's albuterol sulfate were not as high as the spreads from Warrick's albuterol sulfate, due to the high WAC for Warrick's albuterol sulfate. *See* Dey's Response to DOJ's SOF at ¶ 68. Two Dey employees brought the issue of Warrick's higher WAC to the attention of Jerry Wells, the pharmacy director of the Florida Medicaid program, who acknowledged the problem but stated there was nothing he could do about it unless Warrick changed its WAC. *See id.*

On May 30, 1995, Helen Burnham Selenati sent FDB a memo with a new WAC for Dey's albuterol sulfate unit dose products to ensure that they were "…in line with the Warrick WAC values provided by First DataBank and should level the playing field for Medicaid reimbursement." *See id.* The WAC's reported to Red Book and Medispan remained the same. *See* Ex. 406, Figures A-K. In September 1995, another Dey sales representative, met with Mr. Wells again and specifically informed him that Dey's WAC had been adjusted to level the playing field with Warrick. *See id.* There is no evidence in the record that Mr. Wells or anyone else from the Florida Medicaid agency ever complained to Dey regarding the new WACs.

There is also a material issue of fact, as evidence in the record indicates that Dey was not the proximate cause of any claims paid based the allegedly false WACs from at least after December 4, 1995, when Dey advised FDB to publish a lower WAC. *See* Dey's Response to

DOJ's SOF at ¶¶ 68-71. Despite Dey's written request, First DataBank did not implement the lower WACs until January 1, 1998. *See id.* Thus, a jury could find First DataBank's independent decision to continue to publish those WACs after December 4, 1994 was the cause of any "overpayment" to the extent the jury found such payments were anything other than deliberate policy choices.

VI. THE COURT SHOULD GRANT DEY SUMMARY JUDGMENT ON THE GOVERNMENT'S UNJUST ENRICHMENT CLAIM

Dey set out the law on unjust enrichment in its Moving Brief at 37. The Government has failed to come forward with evidence which raises an issue of material fact that there is a "causal nexus" between the alleged wrongful conduct and any enrichment of Dey. *See Holmes Prod. Corp. v. Dana Lighting, Inc.*, 958 F. Supp. 27, 36 (D. Mass. 1997).

In its brief, the Government baldly asserts that "there is no doubt Dey was enriched by its fraudulent scheme" and that Dey "could not have realized [its earnings for the Subject Drugs] had Dey reported accurate prices and denied its customers the benefit of the spread" but points to absolutely no evidence in the record to support these claims. (U.S. Dey Brief at 31). The Government has made no systematic attempt to examine the causal nexus between Dey's sales, its customers, and any ultimate third-party reimbursement. (*Id.*) Its own purported expert on marketing, Matthew Perri, stated at his deposition that he had made no effort to examine the effectiveness of any alleged "marketing the spread" by Dey's sales representatives, and could not opine as to whether the alleged "spread marketing" had any impact on Dey's sales at all. (Ex. 407 at 383:13-384:8; 457:14-458:7).

The evidence cited to raise a triable issue of fact is insufficient. The Government points to Dey's market share for Medicaid-reimbursed ipratropium bromide between 1998 and 2003 as evidence of an enrichment. (*See* US-D-SOF at ¶ 234). However, the Government has failed to

adduce any evidence that any Dey sales representative "marketed the spread" for ipratropium bromide, a product introduced in 1997. (*See id.* at ¶¶ 81-121). Likewise, the contribution margins that the Government cites to themselves indicate that there is no correlation between spreads on Dey's drugs and any benefit to Dey. (*See id.* at ¶ 233). From 1994 to 2003, as a result of generic competition, Dey's albuterol prices were falling while Dey's albuterol AWPs largely remained unchanged, indicating that the spreads on Dey's albuterol were increasing. (*See* SOF at ¶ 72). If the spread conferred an enrichment on Dey, one would expect Dey's albuterol contribution margin to increase as the spread increased. the opposite is true. (*See* US-D-SOF at ¶ 234). Without evidence showing a causal link between the "spread" or "marketing the spread" and Dey's sales, profits or market share, the unjust enrichment claim must fail.

CONCLUSION

For the foregoing reasons, Dey's motion for partial summary judgment should be granted, and the Government's cross motion for partial summary judgment should be denied in all respects.

Dated: August 28, 2009

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2, by causing to be sent, on August 28, 2009, a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ Sarah L. Reid
Sarah L. Reid